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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Poonam SALOTRA, et al

Serial No.: 10/086,184

Filed: February 27, 2002

For: SPECIES-SPECIFIC PCR ASSAY FOR DETECTION OF LEISHMANIA
DONOVANI IN CINICAL SAMPLES OF KALA-AZAR AND POST KALA-AZAR
DERMAL LEISHMANIASIS

Attorney Docket No.: U 013891-8

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT

In response to the Office Communication dated March 25, 2002, please amend the application as follows:

IN THE SPECIFICATION:

Page 4, last paragraph, please delete in entirety and replace with the following:

CERTIFICATE UNDER 37 CFR 1.10

I hereby certify that this paper is being deposited with the United States Postal Service on this date September 25, 2002 in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" Mailing Label Number EV 011024524US addressed to the: Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231

IBIS CARRILLO

(Type or print name of person mailing paper)

Chris Cassella

(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "EXPRESS MAIL" mailing label place thereon prior to mailing 37 CFR 1.16(b).

Fig. 6 Sequence of PCR product (SEQ. ID. NO: 3) with DNA isolated from *L.*

donovani DD8 strain, isolates and clinical samples of KA and PKDL. PCR products obtained with DNA isolated from *L. donovani* DD8 strain, parasite isolates from KA and PKDL patients (2 each) and clinical samples (2 each of KA blood and PKDL tissue) were subjected to sequence analysis. Identical sequence of PCR product was obtained in each case, which matched exactly with the published sequence of a 792 bp kDNA minicircle segment of DD8' strain of *L. donovani* (GenBank accession no. Y11401). Position of primers is indicated in bold.

Page 15, after last line insert the following sequence listing:



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Practitioner's Docket No. U 013891-8

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Poonam SALOTRA, et al

Serial No.: 10/086,184

Filed: February 27, 2002

Group No.: 1645

Examiner:

For: SPECIES-SPECIFIC PCR ASSAY FOR DETECTION OF LEISHMANIA DONOVANI IN CLINICAL SAMPLES OF KALA-AZAR AND POST KALA-AZAR DERMAL LEISHMANIASIS

Assistant Commissioner for Patents

Washington, D. C. 20231

**TRANSMITTAL OF FORMAL DRAWING(S)
PRIOR TO NOTICE OF ALLOWANCE**

Attached please find the formal drawings for this application.

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

*(When using Express Mail, the Express Mail label number is **mandatory**;
Express Mail certification is optional)*

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37 C.F.R. 1.8(a)

37 C.F.R. 1.10*

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TRANSMISSION

- ☐ transmitted by facsimile to the Patent and Trademark Office.

IBIS Carrillo
Signature

Date: September 25, 2002

IBIS CARRILLO

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442

WARNING: "Facsimile transmissions are not permitted and if submitted will not be accorded a date of receipt" for "(4) Drawings submitted under §§ 1.81, 1.83 through 1.85, 1.152, 1.165, 1.174, 1.437..." 37 C.F.R. 1.6(d)(4)

Reg. No. 30,086

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SIGNATURE OF PRACTITIONER

CLIFFORD J. MASS

(type or print name of practitioner)

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26 West 61 Street
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Practitioner's Docket No. U 013891-8

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**Assistant Commissioner for Patents
Washington, D.C. 20231**

TRANSMITTAL OF SUBSTITUTE SPECIFICATION (37 C.F.R. 1.125)

NOTE: A substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by items indicated below. See 37 CFR 1.125(b).

1. Enclosed is a substitute specification for the originally filed specification in this application.

NOTE: The substitute specification must be submitted in clean form without markings as to amended material. 37 CFR 1.125(c)

2. *(complete the following applicable item)*

[X] This substitute specification is submitted in response to a requirement by the Examiner.

OR

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:


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37 C.F.R. 1.10*

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☒ as "Express Mail Post Office to Address"
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(mandatory)

Date: September 25, 2002


Signature

IBIS CARRILLO

(type or print name of person certifying)

(Transmittal of Substitute Specification—page 1 of 2) **9-27**

☐ This substitute specification is being voluntarily submitted, in order to facilitate the processing of the application.

3. Also enclosed is a marked-up copy of the substitute specification showing the matter being added to and the matter being deleted from the specification.

4. Accompanying this transmittal is a statement, as required by 37 C.F.R. 1.125, that the substitute specification transmitted herewith contains no new matter.

Reg. No. 30,086

Tel. No.: 212-708-1890

Customer No.: 00140



SIGNATURE OF PRACTITIONER

CLIFFORD J. MASS

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**Assistant Commissioner for Patents
Washington, D.C. 20231**

**STATEMENT THAT SUBSTITUTE SPECIFICATION
CONTAINS NO NEW MATTER (37 C.F.R. 1.125)**

1. Identification of person making this statement

CLIFFORD J. MASS

(type or print name)

c/o Ladas & Parry

26 West 61st Street

New York, N.Y. 10023

Address

The person making this statement is:

(complete applicable item)

[] the inventor in this application.

[X] the attorney in this application, Registration Number 30,086.

[] other (indicate relationship)

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. 1.10*



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(mandatory)

IBIS CARRILLO

Signature

Date: September 25, 2002

IBIS CARRILLO

(type or print name of person certifying)

(Statement that Substitute Specification Contains No New Matter—page 1 of 2) **9-28**

2. Statement

I hereby state that the accompanying substitute specification contains no new matter over that contained in the above-identified application originally filed.

(complete the following, if applicable)

☐ I further state that the changes made are the same as indicated in the inter-lineated substitute specification also accompanying this statement.

9/25/02
date

[Signature]
Signature of person making statement